

Terumo Medical Corporation  
TSCDII and Trucise  
Section II. 510(k) Summary

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**A. Device Name**

Proprietary Name:	TSCD®II Sterile Tubing Welder with or without Trucise Total System®
Classification:	Transfer Sets (including sterile docking devices) 21 CFR 864.9875 Class II
Product Code:	KSB
Panel:	Division of Hematology
Common Name:	Sterile Tubing Welder with or without accessory information system

**B. Intended Use**

Indications For Use:

The Terumo Sterile Connecting Device (TSCD-II) is used to connect two closed internally sterile components such as a blood collection container, apheresis set, transfer set or needle set by making a sterile weld in the tubing connected to these components. These welds may consist of dry-to-dry, wet-to-dry or wet-to-wet connections. The resulting sterile component may be used in blood collection, blood component processing or transfusion applications. Uses include, but are not limited to:

- Attaching additional blood component containers to a blood collection set to enable component separation or division of the original component into smaller aliquots
- Attaching containers of processing or additive solutions to a blood component to perform a process such as cell washing or freezing or to extend the storage time of the component
- Attaching blood component containers to a pooling set to enable pooling of components from multiple donations.
- Attaching a leukocyte reduction filter to a red blood cell or platelet component container to enable removal of leukocytes from the component
- Attaching a sampling pouch to a blood component container to enable the removal of samples of the component for testing
- Replacing the original needle on a collection set with a new needle of the same or smaller gauge to enable the use of the set or to facilitate a therapeutic procedure such as plasma exchange

The TSCD®-II device is not to be used with tubing connected to a person.

This device is for use by trained individuals in such settings as blood bank laboratories and hospitals.

The Trucise is an optional accessory information system device intended for use with the Terumo Sterile Tubing welders, TSCDII and TSCD, to electronically collect information and provide traceability of each sterile connection made by the welder. The system design and requirements add process control capability to the sterile connection process.

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**C. Device Description**

**TSCDII Sterile Tubing Welder**

The Terumo Sterile Connecting Device (TSCD-II) is used to connect two closed internally sterile components such as a blood collection container, apheresis set, transfer set or needle set by making a sterile weld in the tubing connected to these components. These welds may consist of dry-to-dry, wet-to-dry or wet-to-wet connections. The resulting sterile component may be used in blood collection, blood component processing or transfusion applications. Uses include, but are not limited to:

- Attaching additional blood component containers to a blood collection set to enable component separation or division of the original component into smaller aliquots
- Attaching containers of processing or additive solutions to a blood component to perform a process such as cell washing or freezing or to extend the storage time of the component
- Attaching blood component containers to a pooling set to enable pooling of components from multiple donations.
- Attaching a leukocyte reduction filter to a red blood cell or platelet component container to enable removal of leukocytes from the component
- Attaching a sampling pouch to a blood component container to enable the removal of samples of the component for testing
- Replacing the original needle on a collection set with a new needle of the same or smaller gauge to enable the use of the set or to facilitate a therapeutic procedure such as plasma exchange

The TSCD<sup>®</sup>-II device is not to be used with tubing connected to a person.

This device is for use by trained individuals in such settings as blood bank laboratories and hospitals.

The sterile tubing welder operates as follows: two pieces of tubing to be joined are placed in separate holders. A wafer is heated to a high temperature and melts through the two pieces of tubing. The left-hand tubing holder moves to align the severed tubing with the severed tubing to be joined in the right-hand holder. The wafer then recedes and the two cut ends of the melted tubing are joined together forming a weld that has maintained the internal tubing sterility. After the tubing cools it can be removed from the device.

**Trucise Total System**

The Trucise Total System (Trucise) is an optional accessory information system device intended for use with the Terumo Sterile Tubing Welders, TSCDII and TSCD, to electronically collect information and provide traceability of each sterile connection made by the welder. The system design and requirements add process control capability to the sterile connection process. It provides users an alternate method for capturing data required to document each welding process.

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Each complete setup, or workstation, consists of

- TSCD (cleared under BK970008<sup>1</sup>) or TSCDII sterile tubing welder (subject of this 510k)
- Trucise communication module
- External power supply
- Application software
- Barcode scanner
- Cabling

Trucise does not influence the sterile tubing welding process with the exception of preventing the process to proceed until the applicable information has been entered into the system.

The RS232 activated TSCD<sup>2</sup> or TSCDII welder can operate with or without Trucise attached.

The user prepares the sterile tubing welder to make a weld per the applicable operation procedures. The user then logs into the communication module and selects the sterile connecting process to be performed. The communication module displays step by step instructions. When the user presses the start button on the welder, the Trucise system prompts the user to enter information as required for the particular sterile connecting process. The touch screen will display a series of queries to which the user will respond by using a stylus at the appropriate areas displayed or by using the barcode scanner to scan in the requested information. The Trucise will permit the sterile tubing welder to proceed with making the weld only after the documentation process has been successfully completed by the user.

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<sup>1</sup> The TSCD device was cleared for use with Trucise Total System under BK070018.

<sup>2</sup> Some TSCD devices contain an RS232 port that is not activated. In order for the Trucise accessory to work with a TSCD, the RS233 port must be active. After February 2007 newly manufactured devices have an activated RS232 port. For TSCD devices manufactured prior to that date, a label will be affixed near the port indicating its activation status.

***D. Principle of Operation / Technology***

The sterile tubing welder operates as follows: two pieces of tubing to be joined are placed in separate holders. A wafer is heated to a high temperature and melts through the two pieces of tubing. The left-hand tubing holder moves to align the severed tubing with the severed tubing to be joined in the right-hand holder. The wafer then recedes and the two cut ends of the melted tubing are joined together forming a weld that has maintained the internal tubing sterility. After the tubing cools it can be removed from the device.

The Trucise is an optional accessory information system device intended for use with the Terumo Sterile Tubing Welder, TSCD and TSCDII, to electronically collect information and provide traceability of each sterile connection made by the welder. The system design and requirements add process control capability to the TSCD/TSCDII sterile connection process. It provides users an alternate method for capturing data required to document each welding process.

The user prepares the sterile tubing welder to make a weld per the applicable operation procedures. The user then logs into the communication module and selects the sterile connecting process to be performed. The communication module displays step by step instructions. When the user presses the start button on the welder, the Trucise system prompts the user to enter information as required for the particular sterile connecting process. The touch screen will display a series of queries to which the user will respond by using a stylus at the appropriate areas displayed or by using the barcode scanner to scan in the requested information. The Trucise will permit the sterile tubing welder to proceed with making the weld only after the documentation process has been successfully completed by the user.

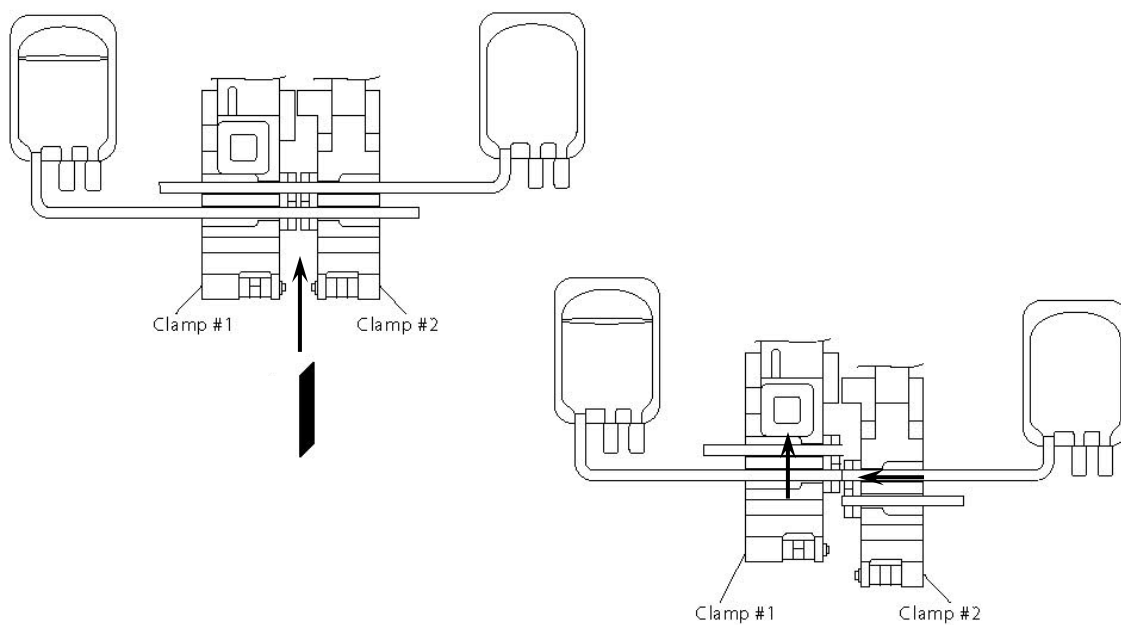
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***E. Design / Materials***

The diagram below depicts how a weld between two pieces of tubing is performed.



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**F. Specifications**

● Specification of tubing to be used:

Tubing material: Polyvinyl chloride (PVC) tubing

Outer Diameter (OD): 3.86 – 5.60 mm (0.152 – 0.220 inches)

Wall Thickness: 0.508 – 1.10 mm (0.019 – 0.043 inches)

Blood Bag Type Tubing:

Outer Diameter (OD): 3.86 – 4.60 mm (0.152 – 0.181 inches)

Wall Thickness: 0.508 – 0.800 mm (0.019 – 0.031 inches)

AVF and Apheresis Type Tubing:

Outer Diameter (OD): 4.9 – 5.60 mm (0.196 – 0.220 inches)

Wall Thickness: 0.75 – 1.10 mm (0.029 – 0.043 inches)

● Physical specifications:

Weight: 6.5 kg (approximately 14 pounds)

Dimension: 224(W) x 177(H) x 342(D) mm (9 X 7 X 13.5 inches)

● Electrical specifications

Power supply: AC100V – AC240V 50/60 Hz

● Performance:

Weld strength: More than 40 N (4.08 kgf)

Weld flow rate: Within 95% flow rate of unwelded tubing

Wafer temperature  
at start of weld: 290 – 310°C

Weld cycle: Approximately 1 weld every 14 seconds

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***G.     Performance***

Substantial equivalence was demonstrated for the following performance attributes:

- Weld integrity strength
- Weld sterility
- Fluid transfer
- Particulates
- Humidity and temperature testing
- Altitude testing

***H.     Additional Safety Information***

Substantial equivalence was established regarding:

- Biocompatibility of welded tubing
- Electrical Safety
- Software Validation

***I.     Substantial Equivalence***

The TSCDII sterile tubing welder subject of this 510(k) is substantially equivalent to the TSCDII sterile tubing welder manufactured by Terumo Corporation (BK040082) in intended use, design/materials, principles of operation/technology and performance.

The Trucise Total System subject of this 510(k) is substantially equivalent to the Trucise Total System manufactured by Terumo Medical Corporation (BK070018) in intended use, design, principles of operation/technology and performance.

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**J. Submitter Information**

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